7.0

510(k) SUMMARY K010559

DEC 2 0 2001

SAUFLON MULTI™ LENS CARE SYSTEM

1. **Submitted by:**

Sauflon Pharmaceuticals Ltd
49-53 York Street
Twickenham
TW1 3LP
UK

Official correspondent: Ligia Delacruz, PhD
Regulatory Affairs Manager

2. **Device name**

Common Name: MULTI™ Lens Care System

Proprietary Name: Sauflon MULTI™ Lens Care System

3. **Classification:** Class II
(Performance Standards)
21 CFR 886.5928
Soft (hydrophilic) contact lens solution

4. **Substantial Equivalence:** The product is substantially equivalent to the currently marketed AOsept Disinfection System

5. **Device Description:** MULTI™ is a Hydrogen peroxide disinfection system consisting of a sterile 3% Hydrogen Peroxide solution which is used with a barrel lens case containing a built-in platinum disc neutraliser. MULTI™ solution is stabilised with phosphonic acid, buffered with phosphates and contains a surfactant cleaner.

6. **Intended use:** MULTI™ is a multi-function system indicated for use in the daily cleaning, chemical (not heat) disinfection, neutralisation and storage of soft (hydrophilic) contact lenses replaced in 30 days or less, as recommended by the eye care practitioner

7.1 Comparison to the predicate device

Ingredient	MULTI™	AOSept
Salt	Sodium Chloride	Sodium Chloride
Stabiliser	Phosphonic acid	Phosphonic acid
Buffer	Phosphates	Phosphates
Surfactant	Poloxamer	Not present
Antimicrobial & Disinfectant	Hydrogen peroxide 3%	Hydrogen peroxide 3%
Solvent	Purified water qs	Purified water qs
Other	Sterile - isotonic	Sterile - isotonic

7.2 Pre-clinical Testing

Solution compatibility
The compatibility of the Sauflon MULTI™ solution was demonstrated by cycling lenses through 30 cycles of simulated use, using the Sauflon MULTI™ solution for cleaning, rinsing, disinfecting and storing. Parameters of lenses were measured before and after the 30 cycles, and no differences were found.

Toxicology

The Sauflon MULTI™ solution was shown to be non-toxic in all cytotxicity, systemic toxicity and ocular irritation and acute oral toxicity tests. Additional testing, (cytotoxicity, systemic toxicity and ocular irritation) were carried out to verify the safety of the solution in the contract manufacturers container.

MULTI™ SOLUTION

Agar Overlay Cytotoxicity
Representative lenses from all four of soft (hydrophilic) lens types were exposed to the Sauflon MULTI™ solution for 24 hours, then tested in a direct contact cytotoxicity assay. All test lens types were noncytotoxic

Acute Oral toxicity
The Sauflon MULTI™ test solution was evaluated for acute oral toxicity by intubation in healthy rats at 5ml/kg body weight. The animals were weighted prior to intubation, at 7 days, and at 14 days. Animals were observed immediately after intubation after 2 and 4 hours, then daily for 14 days. There were no treatment – related effects or deaths. Sauflon MULTI™ caused no adverse effects when administered to rats at a single oral dose of 5ml/kg body weight.

Acute Ocular irritation
The Sauflon MULTI™ test solution was instilled directly into one eye of each of three rabbits, the other eye receiving sterile water as a control. Examinations over 72 hours showed no differences between test and control eyes, with no evidence of ocular irritation with either the test or control solutions. The test solution therefore meets the requirements of the acute ocular irritation test.

MULTI™ SOLUTION CONTAINER
The Sauflon Multi solution container components meet the requirements of the USP<661> for containers and closures for ophthalmic preparations, and it has been confirmed by the appropriate tests (i.e the cytotoxicity, occular irritancy, and systemic toxicity tests).

MULTI™ LENS CASE
The components of the lens case also comply with the requirements of the USP <661>, as shown by the cytotoxicity, ocular irritation and systemic injection tests.

Microbiology

Sterility
The Sauflon MULTI™ soft (hydrophilic) contact lens solution passed the requirements of sterility testing.

Preservative efficacy
The Saulfon MULTI™ soft (hydrophilic) Contact Lens Solution passed the requirements of the preservative efficacy test with rechallenge at 14 days.

Disinfection Efficacy
The Sauflon MULTI™ Soft (hydrophillic) Contact Lens Solution passed the requirements of both the Stand-alone with organic load Disinfection Test and the Regimen Test.

Stability
The solution has currently passed accelerated stability testing corresponding to a shelf life of 24 months. All three stability batches passed Sterility, Preservative Efficacy and Disinfection efficacy testing at the end of the stability study, thus showing that the product had maintained its sterile integrity, and the peroxide had retained its preservative and disinfection power.

7.3 Clinical Studies

A clinical trial of 3 months usage of Sauflon MULTI™ Lens Care System by 51 subjects, wearing soft (hydrophilic) contact lenses replaced every thirty days of either group II and IV, compared to 22 control subjects using AOsept disinfection system, showed the safety, acceptability and substantial equivalence of MULTI™ Lens Care System to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Sauflon Pharmaceuticals Ltd.
C/O Dr. Ligia Delacruz, Regulatory Affairs Manager
49-53 York Street
Twickenham, Middlesex
TW1 3LP
United Kingdom

Re: K010559
Trade/Device Name: Sauflon MULTI™ Lens Care System (for soft lenses replaced in 30 days or less)
Regulation Number: 21 CFR 866.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: November 9, 2001
Received: November 13, 2001

Dear Dr. Delacruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010559

Device Name: MULTI™ Lens Care System

Indications For Use: MULTI™ is a multi-function system indicated for use in the daily cleaning, chemical (not heat) disinfection, neutralisation and storage of soft (hydrophilic) contact lenses replaced in 30 days or less, as recommended by the eye care practitioner

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Karen Warburton 12/19/01

Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K010559

Prescription Use _____ OR Over-The Counter X

(Per 21 CFR 801.109)

JS